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Attorney for Plaintiffs,
Christine Contreras Individually and as Mother,
General Guardian of A.C. a minor

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CHRISTINE CONTRERAS
INDIVIDUALLY AND AS
MOTHER, GENERAL
GUARDIAN OF A.C., A MINOR

Plaintiffs,

vs.

BIG LOTS, INC., DOLLAR
GENERAL CORPORATION, CVS
PHARMACY, INC.,

Defendants.

Case No.:

COMPLAINT

(Jury Trial Demanded)

COMPLAINT

Plaintiff Christine Contreras and Plaintiff A.C., pursuant to Fed. R. Civ. P. 17(c)(1)(A), by and through their undersigned counsel, bring this Complaint for damages against Defendants Big Lots, Inc. (hereinafter “Big Lots”), Dollar General Corporation (hereinafter “Dollar General”) and CVS Pharmacy, Inc. (hereinafter, “CVS”) (each, a “Defendant” and collectively, “Defendants”) and in support state the following:

1 1. This is an action brought on behalf of Plaintiffs, Christine Contreras
2 (hereinafter, "Plaintiff Mother"), the mother and guardian of A.C. (hereinafter,
3 "Plaintiff Child"), a minor, arising out of the failure of Defendants to warn about the
4 dangers of prenatal exposure to Paracetamol, also known as Acetaminophen
5 (hereinafter "APAP") and its propensity to cause autism spectrum disorder
6 (hereinafter, "ASD") and attention deficit/hyperactivity disorder (hereinafter,
7 "ADHD") in children. As a result, Plaintiffs have suffered permanent injuries and
8 significant pain and suffering, emotional distress, lost wages and earning capacity,
9 and diminished quality of life. Plaintiffs respectfully seek all damages to which they
10 may be legally entitled.

11 2. Defendants entirely failed their duty to adequately warn of the hazards
12 of prenatal exposure to APAP, which was a direct and proximate cause of Plaintiffs'
13 injuries and associated damages.

14 **STATEMENT OF PARTIES**

15 3. At all material times Plaintiffs have been citizens and residents of Los
16 Angeles County, California, and the United States.

17 4. Big Lots is incorporated in Ohio, with its principal place of business
18 also in Ohio.

19 5. Dollar General is incorporated in Tennessee, with its principal place of
20 business also in Tennessee.

21 6. CVS is incorporated in Delaware, with its principal place of business
22 also in Rhode Island.

23 7. Defendants are American companies involved in the research,
24 development, testing, manufacture, labeling, production, marketing, promotion,
25 and/or sale of APAP through their over-the-counter store brands (hereinafter, the
26 "Store Brand APAP").

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8. Defendants are individually, and jointly and severally liable to Plaintiffs for damages they suffered, arising from Defendants' design, manufacture, marketing, labeling, distribution, sale, and placement of the defective Store Brand APAP into the market, effectuated directly and indirectly through their agents, servants, employees, and/or owners, all acting within the course and scope of their agencies, services, employments, and/or ownership.

9. Defendants are vicariously liable for the acts and/or omissions of their employees and/or agents, who were at all material times acting on behalf of Defendants and within the scope of their employment or agency.

VENUE AND JURISDICTION

10. This Court has subject-matter jurisdiction under 28 U.S.C. § 1332(a), based on complete diversity of citizenship between Plaintiffs and Defendants. *See supra* ¶¶ 3–4.

11. The amount in controversy exceeds \$75,000.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the events or omissions giving rise to Plaintiffs' claims occurred in this judicial district.

13. Defendants have and continue to conduct substantial business in the State of California and in this District, distribute the Store Brand APAP in this District, receive substantial compensation and profits from sales of the Store Brand APAP in this District, and have made material omissions and misrepresentations and breaches of warranties in this District, so as to subject Defendants to in personam jurisdiction in this District.

Each Defendant is registered to transact business in California.

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FACTS COMMON TO ALL COUNTS

**APAP Is Marketed as the Safe Pain Reliever for Pregnant Women,
but APAP Can Cause Neurodevelopment Disorders in Children, such as ASD
and ADHD**

14. APAP was initially discovered in the late 1800's.

15. APAP is sold in billions of units annually in North America alone.

16. APAP is widely used by pregnant women to relieve pain during the term of their pregnancy.

17. APAP was introduced to the US market in 1955 as the first aspirin-free pain reliever.

18. APAP has long been marketed as the safest, and the *only* appropriate, over-the-counter pain relief drug on the market for pregnant women.

19. More than 65% of women in the United States use APAP during pregnancy.

20. Based upon information and belief, a majority of women who use APAP during pregnancy do so electively for the treatment of headaches, muscle pain, back pain, and infection.

21. These pregnant women electively choose to take APAP because Defendants have marketed APAP as a safe pain reliever for pregnant women.

22. However, increasing experimental and epidemiological research shows that prenatal exposure to APAP alters fetal development, which significantly increases the risks of neurodevelopmental disorders, including but not limited to, autism spectrum disorder ("ASD") and attention-deficit/hyperactivity disorder.

23. Undisturbed development of the human brain in utero is vital to the health and wellness of a child's development. The human brain is vulnerable and extremely sensitive in utero.

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1 24. During this sensitive time-period in utero, certain chemicals have been
2 found to cause permanent brain injury at low exposure levels.

3 25. Once ingested by the mother, APAP is known to readily cross the
4 placenta and blood-brain barrier.

5 26. ASD is a serious neurological and developmental disorder that affects
6 how people interact with others, communicate, learn, and behave.

7 27. There are three functional levels of ASD, with Level 1 requiring
8 support with activities of daily living, Level 2 requiring substantial support with
9 activities of daily living, and Level 3 requiring very substantial support with
10 activities of daily living.

11 28. Treatments for ASD include behavioral management therapy, cognitive
12 behavior therapy, joint attention therapies, medications, occupational therapy,
13 physical therapy, social skill training, and speech-language therapy. Treatment for
14 ASD lasts a lifetime, as there is no cure.

15 29. ADHD is a chronic neurodevelopmental disorder resulting in attention
16 difficulty, hyperactivity, and impulsiveness.

17 30. ADHD begins in childhood and persists through adulthood. ADHD
18 contributes to low self-esteem, troubled relationships, and difficulty with school,
19 work, and familial relationships.

20 31. Treatments for ADHD, include, but are not limited to, chronic
21 medication usage and various therapies.

22 32. Treatment for ADHD lasts a lifetime, as there is no cure.

23 33. Adults with childhood ADHD are expected to earn \$1.25 million less
24 than adults without ADHD over their lifetime, potentially reaching retirement with
25 up to a 75 percent lower net worth.

26 34. In or around 2018, the Center for Disease Control and Prevention
27 (“CDC”) found that 1 in 44 (2.3%) 8-year-old children have been diagnosed with
28 ASD.

1 35. This represents an increase from a prior CDC finding that 1 in 68 U.S.
2 children born in 2002 have ASD, which already represented a more than a 100%
3 increase compared with children born a decade prior.

4 36. As of 2019, 8.8% of children had been diagnosed with ADHD, or
5 roughly 325,000 children per year.

6 37. Parental awareness and changes in diagnoses do not account for the
7 rapid rise in these diagnoses of ASD.

8 38. Rather, neurotic exposures, such as prenatal APAP exposure, explain a
9 trending increase in diagnosis.

10 39. For years, the scientific community has published studies showing that
11 prenatal ingestion of APAP can cause ASD and ADHD.

12 40. For instance, since 2013, there have been six European birth cohort
13 studies, examining over 70,000 mother-child pairs, showing the association between
14 prenatal use of APAP and ASD and ADHD.

15 41. At this time, the overall body of scientific evidence shows that prenatal
16 use of APAP can cause ASD and ADHD in the child.

17 42. During all relevant times herein, Defendants were engaged in the
18 business of manufacturing and selling the APAP Products in the United States, and
19 the weight of the scientific evidence available showed prenatal exposure to APAP
20 significantly increases the risk of neurodevelopmental disorders in children exposed
21 to APAP prenatally, including but not limited to ASD and ADHD.

22 43. The scientific evidence regarding the risks of in utero exposure of
23 APAP was available to Defendants, and Defendants knew or should have known
24 that prenatal use of APAP can cause ASD and ADHD.

25 44. Based on information and belief, Defendants have concealed the
26 prenatal APAP exposure-neurodevelopmental link from consumers, like Plaintiff
27 Mother, in part by not reporting the link to the FDA, which relies on drug
28 manufacturers to bring new information about a drug to the agency's attention.

1 45. Moreover, despite knowing that prenatal use of APAP can cause ASD
2 and ADHD, Defendants continue to market the APAP Products as the safe pain
3 reliever for pregnant women, making mothers believe they are choosing a safe drug
4 for even minor aches, pains, and headaches.

5
6 **Plaintiff Mother Took Store Brand APAP while Pregnant,**
7 **and It Caused ASD and ADHD in Plaintiff Child**

8 46. Plaintiff Mother began using the Store Brand APAP in or around
9 January 2010, when she was pregnant with Plaintiff Child, through October 2010
10 when Plaintiff Child was born.

11 47. Throughout Plaintiff Mother's pregnancy, she purchased and took the
12 Store Brand APAP from Defendants' stores, Big Lots, Dollar General, and CVS.

13 48. Plaintiff Mother purchased and took the Store Brand APAP in Los
14 Angeles County, California.

15 49. Plaintiff Mother electively took the Store Brand APAP while pregnant.

16 50. Plaintiff Mother believed it was safe for her to take the Store Brand
17 APAP during her pregnancy.

18 51. There is no warning on the Store Brand APAP labels specifically
19 addressing the risks of a child developing ASD or ADHD if a mother ingests APAP
20 while pregnant.

21 52. Had Plaintiff Mother known of the risk of taking APAP while pregnant,
22 specifically that it could cause ASD and ADHD in her child, she would not have
23 taken the Store Brand APAP.

24 53. Plaintiff Child was born on October 14, 2006.

25 54. Plaintiff Mother started to have concerns about Plaintiff Child's
26 development when he was around nine or ten months old.

27 55. At that time, Plaintiff Child was not responding to his name and began
28 crawling differently.

1 56. Plaintiff Child also had heightened sensory issues.

2 57. Plaintiff Mother noticed differences between the way her first-born
3 child acted when he was that age and Plaintiff Child.

4 58. Plaintiff Child was diagnosed with ASD when he was eighteen months
5 old.

6 59. Plaintiff was also diagnosed with ADHD.

7 60. Plaintiff Mother is Plaintiff Child's primary care giver and works part-
8 time.

9 61. Plaintiff Child requires 24-hour supervision.

10 62. Plaintiff Child is non-verbal and does not know how to write.

11 63. Plaintiff Child needs help with basic hygiene.

12 64. He does not understand the concept of danger.

13 65. Plaintiff Child attends behavioral therapy six days a week because of
14 his ASD.

15 66. Plaintiff Child attends occupational therapy because of his ASD.

16 67. Plaintiff Child will never be able to live independently.

17 68. Plaintiff Child's ASD and ADHD have placed an incredible strain on
18 Plaintiff Mother, and she has significant concerns for his future.

19 **ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS**

20 69. Due to Defendants' acts of fraudulent concealment, Defendants are
21 estopped from relying on any statutes of limitations or repose. Such acts include
22 Defendants' intentional concealment from Plaintiff Mother and the general public
23 that APAP is defective when there is prenatal exposure, while continuing to market
24 the Store Brand APAP with the adverse effects described in this Complaint.

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1 70. Given Defendants' affirmative actions of concealment by failing to
2 disclose information about the defects known to them but not the public—
3 information over which Defendants had exclusive control—and because Plaintiff
4 Mother could not reasonably have known that the Store Brand APAP was defective,
5 Defendants are estopped from relying on any statutes of limitations that might
6 otherwise be applicable to the claims asserted in this Complaint.

7 **COUNT I: STRICT LIABILITY – FAILURE TO WARN**

8 71. Plaintiffs incorporate by reference the allegations in all prior
9 paragraphs.

10 72. At the time of Plaintiffs' injuries, the Store Brand APAP was defective
11 and unreasonably dangerous to foreseeable consumers, including Plaintiff Mother,
12 because they lacked an adequate warning.

13 73. At all relevant times, Defendants engaged in the business of testing,
14 developing, designing, manufacturing, marketing, labeling, selling, distributing, and
15 promoting the Store Brand APAP, which was defective and unreasonably dangerous
16 to consumers, including Plaintiff Mother, because they did not contain adequate
17 warnings or instructions concerning the dangerous characteristics of ingesting APAP
18 during pregnancy. These actions were under the ultimate control and supervision of
19 Defendants. At all relevant times, Defendants registered, researched, manufactured,
20 distributed, marketed, labeled, promoted, and sold the Store Brand APAP within this
21 District and aimed the marketing at the ultimate consumer. Defendants were at all
22 relevant times involved in the retail and promotion of the Store Brand APAP
23 marketed and sold in this District.

24 74. Defendants had a duty to warn of the risks associated with the use of
25 the Store Brand APAP.

26 75. The Store Brand APAP ingested by Plaintiff Mother during pregnancy
27 was in the same or substantially similar condition as it was when it left possession
28 of the Defendants.

1 76. Defendants expected and intended the Store Brand APAP to reach users
2 such as Plaintiff Mother in the condition in which the Store Brand APAP was sold.

3 77. Plaintiff Mother did not materially alter the Store Brand APAP prior to
4 ingestion.

5 78. Plaintiff Mother ingested the Store Brand APAP as indicated on the
6 Store Brand APAP labels.

7 79. Plaintiff Mother was unaware of the defects and dangers of the Store
8 Brand APAP and was unaware that prenatal exposure increases the risk of brain and
9 behavioral development of children in utero.

10 80. The labels on the Store Brand APAP to consumers lack any warning
11 specific to pregnant women. The information that Defendants did provide or
12 communicate failed to contain relevant warnings, hazards, and precautions that
13 would have enabled consumers such as Plaintiff Mother to utilize the products safely
14 and with adequate protection, or decide to not ingest the Store Brand APAP at all.

15 81. This alleged failure to warn is not limited to the information contained
16 on the Store Brand APAP labeling. Defendants were able, in accord with federal
17 law, to comply with relevant state law by disclosing the known risks associated with
18 APAP through other non-labeling mediums, i.e., promotion, advertisements, public
19 service announcements, and/or public information sources. But Defendants did not
20 disclose these known risks through any medium.

21 82. At all relevant times, Defendants had a duty to properly test, develop,
22 design, manufacture, inspect, package, label, market, promote, sell, distribute,
23 maintain, and supply the Store Brand APAP; provide proper warnings for the Store
24 Brand APAP; and take such steps as necessary to ensure the Store Brand APAP did
25 not cause users and consumers, and their children, to suffer from unreasonable and
26 dangerous risks. Defendants had a continuing duty to warn Plaintiff Mother of
27 dangers associated with APAP. Each Defendant, as a manufacturer, seller, and/or
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1 distributor of pharmaceutical medication, is held to the knowledge of an expert in
2 the field.

3 83. At the time of manufacture, Defendants could have provided the
4 warnings or instructions regarding the full and complete risks of the Store Brand
5 APAP because Defendants knew or should have known of the unreasonable risks of
6 ASD and ADHD associated with prenatal exposure to and/or the use of such
7 products.

8 84. At all relevant times, Defendants failed and deliberately refused to
9 investigate, study, test, or minimize the dangers to consumers of the Store Brand
10 APAP and to those who would foreseeably use or be harmed by the Store Brand
11 APAP, including Plaintiffs.

12 85. Defendants failed to adequately warn consumers, like Plaintiff Mother,
13 about the significant increased risk of neurodevelopmental disorders in children
14 exposed to APAP prenatally, including but not limited to ASD and ADHD.

15 86. Defendants failed to adequately inform reasonably foreseeable
16 consumers, like Plaintiff Mother, of the proper usage of the Store Brand APAP.

17 87. Even though Defendants knew or should have known that APAP posed
18 a grave risk of harm to Plaintiff Child, Defendants failed to exercise reasonable care
19 to warn of the dangerous risks associated with use and prenatal exposure.

20 88. Plaintiff Mother was exposed to the Store Brand APAP without
21 knowledge of their dangerous characteristics.

22 89. At all relevant times, Plaintiff Mother used and/or was exposed to the
23 use of the Store Brand APAP while using them for their intended or reasonably
24 foreseeable purposes, without knowledge of their dangerous characteristics.

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1 90. Plaintiff Mother could not have reasonably discovered the defects and
2 risks associated with the Store Brand APAP prior to or at the time of Plaintiff
3 consuming APAP. Plaintiff Mother relied upon the skill, superior knowledge, and
4 judgment of Defendants to know about and disclose serious health risks associated
5 with using the Store Brand APAP.

6 91. If Plaintiff Mother had been properly warned of the defects, dangers,
7 and risks associated with prenatal exposure to APAP, Plaintiff Mother would have
8 decided to not ingest the Store Brand APAP while pregnant.

9 92. Defendants are liable to Plaintiffs for injuries caused by Defendants'
10 negligent or willful failure, as described above, to provide adequate warnings or
11 other relevant information and data regarding the appropriate use of the Store Brand
12 APAP and the risks associated with the use of APAP.

13 93. As a direct and proximate result of Defendants' placing defective Store
14 Brand APAP into the stream of commerce, and Plaintiff Mother's ingestion of the
15 Store Brand APAP during pregnancy, Plaintiff Child was exposed to APAP
16 prenatally, causing her to develop ASD and ADHD.

17 94. As a direct and proximate result of Defendants' placing defective Store
18 Brand APAP into the stream of commerce, Plaintiffs have suffered permanent
19 injuries, significant pain and suffering, emotional distress, lost wages and earning
20 capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to
21 which they may be legally entitled.

22 **COUNT II: NEGLIGENCE**

23 95. Plaintiffs incorporate by reference the allegations in all prior
24 paragraphs.

25 96. Although Defendants had a duty to use reasonable care in testing,
26 developing, designing, manufacturing, marketing, labeling, selling, distributing,
27 promoting, and preparing written instructions and warnings for the Store Brand
28 APAP, Defendants failed to do so.

1 97. Defendants, directly or indirectly, caused the Store Brand APAP to be
2 sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff
3 Mother. At all relevant times, Defendants registered, researched, manufactured,
4 distributed, marketed, promoted, and sold the Store Brand APAP within this district
5 and aimed at a consumer market within this district.

6 98. Defendants knew, or in the exercise of reasonable care should have
7 known, that the Store Brand APAP was defectively and unreasonably designed
8 and/or manufactured, and/or marketed, and was unreasonably dangerous and likely
9 to injure persons that were prenatally exposed to them. Defendants knew or should
10 have known that Plaintiff Mother was unaware of the dangers and defects inherent
11 in the Store Brand APAP when she was ingesting them during her pregnancy with
12 Plaintiff Child.

13 99. At all relevant times, Defendants had a duty to exercise reasonable care
14 in the marketing, advertisement, promotion, and sale of the Store Brand APAP.
15 Defendants' duty of care owed to consumers and the general public included
16 providing accurate, true, and correct information concerning the risks of using APAP
17 during pregnancy and appropriate, complete, and accurate warnings concerning the
18 potential adverse effects of APAP and, in particular, the significantly increased risk
19 of causing neurodevelopmental disorders in children through prenatal exposure to
20 APAP.

21 100. At all relevant times, Defendants knew or, in the exercise of reasonable
22 care, should have known of the hazards and dangers of APAP ingestion while
23 pregnant and, specifically, the significantly increased risk of causing
24 neurodevelopmental disorders in children through prenatal exposure to APAP.

25 101. Defendants failed to provide any kind of warning to pregnant
26 consumers, like Plaintiff Mother, about the significantly increased risk of causing
27 neurodevelopmental disorders in children through prenatal exposure to APAP.
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1 102. Accordingly, at all relevant times, Defendants knew or, in the exercise
2 of reasonable care, should have known that use of the Store Brand APAP could cause
3 Plaintiffs' injuries, and thus, create a dangerous and unreasonable risk of injury to
4 the users of these products, including Plaintiffs.

5 103. As such, Defendants breached their duty of reasonable care and failed
6 to exercise ordinary care in the design, research, development, manufacture, testing,
7 marketing, labeling, supply, promotion, advertisement, packaging, sale, and
8 distribution of the Store Brand APAP, in that Defendants manufactured and
9 produced defective Store Brand APAP, which carry the significantly increased risk
10 of causing neurodevelopmental disorders in children through prenatal exposure to
11 APAP; knew or had reason to know of the defects inherent in the Store Brand APAP;
12 knew or had reason to know that a user's or consumer's use of the Store Brand APAP
13 created a significant risk of harm and unreasonably dangerous side effects; and failed
14 to prevent or adequately warn of these risks and injuries.

15 104. Defendants had a duty to disclose the truth about the risks associated
16 with APAP in their promotional efforts outside of the context of labeling.
17 Defendants were negligent in their promotion of APAP outside of the labeling
18 context by failing to disclose material risk information as part of their promotion and
19 marketing of the Store Brand APAP, including through the internet, television, and
20 print advertisements.

21 105. Despite Defendants' ability and means to investigate, study, and test
22 the Store Brand APAP and to provide adequate warnings, Defendants failed to do
23 so. Indeed, Defendants wrongfully concealed information and further made false
24 and/or misleading statements concerning the safety and use of APAP.

25 106. Defendants' negligence included:

- 26 a. Manufacturing, producing, promoting, formulating, creating,
27 developing, designing, selling, and/or distributing the Store Brand
28 APAP while negligently and/or intentionally concealing and failing to

1 disclose the results of trials, tests, and studies of APAP and the
2 significantly increased risk of causing neurodevelopmental disorders in
3 children through prenatal exposure to APAP, and, consequently, the
4 risk of serious harm associated with human use of APAP during
5 pregnancy;

- 6 b. Failing to undertake sufficient studies and conduct necessary tests to
7 determine whether or not the Store Brand APAP were safe for its
8 intended consumer use and unborn children;
- 9 c. Failing to provide adequate instructions, guidelines, and safety
10 precautions to those persons Defendants could reasonably foresee
11 would use the Store Brand APAP;
- 12 d. Failing to disclose to Plaintiff Mother, users, consumers, and the
13 general public that use of APAP during pregnancy presents severe risks
14 of neurodevelopmental disorders in children exposed to APAP
15 prenatally;
- 16 e. Failing to warn Plaintiff Mother, users, consumers, and the general
17 public that the Store Brand APAP' risk of harm was unreasonable and
18 that there were safer and effective alternative medications or treatments
19 available to Plaintiff Mother and other users and/or consumers;
- 20 f. Representing that the Store Brand APAP were safe for their intended
21 purposes for pregnant women when, in fact, Defendants knew or should
22 have known the Store Brand APAP was not safe for their intended
23 purposes;
- 24 g. Declining to make or propose any changes to the Store Brand APAP'
25 labeling or other promotional materials that would alert users,
26 consumers, and the general public of the risks of APAP, including to
27 pregnant women;
- 28

- 1 h. Advertising, marketing, and recommending the use of the Store Brand
2 APAP, while concealing and failing to disclose or warn of the dangers
3 known by Defendants to be caused by the use of or exposure to APAP;
4 i. Continuing to disseminate information to their consumers and the
5 general public, which indicates or implies that the Store Brand APAP
6 are not unsafe for pregnant consumer use; and
7 j. Continuing the manufacture and sale of the Store Brand APAP with the
8 knowledge that the Store Brand APAP was unreasonably unsafe and
9 dangerous.

10 107. Defendants knew and/or should have known that it was foreseeable that
11 children such as Plaintiff Child would suffer injuries as a result of Defendants'
12 failure to exercise ordinary care in the manufacturing, marketing, labeling,
13 distribution, and sale of the Store Brand APAP to consumers, like Plaintiff Mother.

14 108. Plaintiff Mother did not know the nature and extent of the injuries that
15 could result in her child from the intended use of and/or exposure to APAP
16 prenatally.

17 109. Defendants' negligence was the proximate cause of Plaintiffs' injuries,
18 i.e., absent Defendants' negligence, Plaintiff Child would not have developed ASD
19 and ADHD.

20 110. Defendants' conduct, as described above, was reckless. Defendants
21 regularly risked exposing Plaintiff Mother to the Store Brand APAP while pregnant
22 with Plaintiff Child, with full knowledge of the dangers of the Store Brand APAP
23 and that it could cause ASD and ADHD in Plaintiff Child. Defendants made
24 conscious decisions not to redesign, re-label, warn, or inform the unsuspecting
25 public, including Plaintiff Mother. Defendants' reckless conduct therefore warrants
26 an award of punitive damages.

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111. As a direct and proximate result of Defendants placing the defective Store Brand APAP into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT III: BREACH OF EXPRESS WARRANTY

112. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

113. At all material times, Defendants manufactured, marketed, sold, distributed, and otherwise placed into the stream of commerce the Store Brand APAP. These actions were under the ultimate control and supervision of Defendants.

114. In advertising, marketing, and promoting the Store Brand APAP to consumers, like Plaintiff Mother, Defendants expressly warranted that the Store Brand APAP was safe for use and reasonably fit for their intended purposes. In advertising, marketing, and otherwise promoting the Store Brand APAP, Defendants intended for pregnant consumers to rely upon their representations regarding safety and fitness, in an effort to induce them to purchase and consume the Store Brand APAP during pregnancy to relieve pain.

115. Defendants expressly warranted to Plaintiff Mother and pregnant consumers that the Store Brand APAP was safe for ingestion during pregnancy.

116. Defendants had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of the Store Brand APAP, including a duty to:

- a. ensure that the Store Brand APAP did not cause users and their unborn children unreasonably dangerous side effects;
- b. warn of dangerous and potentially incurable side effects; and

1 c. disclose adverse material facts, such as the true risks associated with
2 the use of and exposure to APAP during pregnancy, when making
3 representations to users, consumers, and the general public, including
4 Plaintiff Mother.

5 117. Defendants had the ability to properly disclose the risks associated with
6 APAP usage during pregnancy through multiple channels, not just labeling.

7 118. At all relevant times, Defendants expressly represented and warranted
8 to the purchasers of the Store Brand APAP, by and through statements made by
9 Defendants in labels, publications, brochures, and other written materials intended
10 for consumers and the general public, that the Store Brand APAP was safe to human
11 health and the environment, effective, fit, and proper for their intended use.
12 Defendants advertised, labeled, marketed, and promoted the Store Brand APAP,
13 representing the quality to consumers and the public in such a way as to induce their
14 purchases or use, thereby making an express warranty that the Store Brand APAP
15 would conform to the representations.

16 119. The representations about the Store Brand APAP, as set forth herein,
17 contained or constituted affirmations of fact or promises made by the seller to the
18 buyer, which related to the goods and became part of the basis of the bargain,
19 creating an express warranty that the goods would conform to the representations.

20 120. Defendants breached express representations and warranties made to
21 Plaintiff Mother, with respect to the Store Brand APAP, including the following:

- 22 a. Defendants represented through their labeling, advertising, and
23 marketing materials that the Store Brand APAP was safe, and
24 intentionally withheld and concealed information about the risks of
25 serious injury associated with use of APAP and by expressly limiting
26 the risks associated with use within their warnings and labels; and
27 b. Defendants represented that the Store Brand APAP was safe for use and
28 intentionally concealed information that demonstrated that APAP

1 carries the significantly increased risk of causing neurodevelopmental
2 disorders in children through prenatal exposure to APAP, and that the
3 Store Brand APAP, therefore, was not safer than alternatives available
4 on the market.

5 121. Plaintiff Mother detrimentally relied on the express warranties and
6 representations of Defendants concerning the safety and/or risk profile of APAP in
7 deciding to purchase the Store Brand APAP. Plaintiff Mother reasonably relied
8 upon Defendants to disclose known defects, risks, dangers, and side effects of
9 APAP. Plaintiff Mother would not have purchased or used the Store Brand APAP
10 had Defendants properly disclosed the risks associated with the Store Brand APAP,
11 either through advertising, labeling, or any other form of disclosure.

12 122. Plaintiff Mother had no knowledge of the falsity or incompleteness of
13 Defendants' statements and representations concerning the Store Brand APAP.

14 123. Plaintiff Mother used and/or was exposed to APAP as researched,
15 developed, designed, tested, manufactured, inspected, labeled, distributed,
16 packaged, marketed, promoted, sold, or otherwise released into the stream of
17 commerce by Defendants.

18 124. Had the warnings, labels, advertisements, or promotional material for
19 the Store Brand APAP accurately and adequately set forth the true risks associated
20 with the use of such Products, including Plaintiffs' injuries, rather than expressly
21 excluding such information and warranting that the Store Brand APAP was safe for
22 their intended use, Plaintiffs could have avoided the injuries complained of herein.

23 125. As a direct and proximate result of Defendants' breach of express
24 warranty, Plaintiffs have suffered permanent injuries, significant pain and suffering,
25 emotional distress, lost wages and earning capacity, and diminished quality of life.
26 Plaintiffs respectfully seek all damages to which they may be legally entitled.

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COUNT IV: BREACH OF IMPLIED WARRANTY

126. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

127. At all material times, Defendants manufactured, marketed, sold, distributed, and otherwise placed the Store Brand APAP into the stream of commerce.

128. At all material times, Defendants intended for the Store Brand APAP to be consumed and ingested by pregnant women, like Plaintiff Mother; and Defendants impliedly warranted that the Store Brand APAP and their component parts were of merchantable quality, safe, fit for such use, and adequately tested.

129. Defendants were aware that consumers, including Plaintiff Mother, would consume and ingest the Store Brand APAP as directed by the Products' labels and promotional materials. Therefore, Plaintiff Mother was a foreseeable user of the Store Brand APAP.

130. But Defendants failed to disclose that APAP has dangerous propensities when used as intended and that use of the Store Brand APAP carries an increased risk of developing severe injuries, including Plaintiff Child's injuries.

131. The Store Brand APAP was expected to reach, and did in fact reach consumers, including Plaintiff Mother, without substantial change in the condition in which they were manufactured and sold by Defendants.

132. Plaintiff Mother was an intended beneficiary of the implied warranties made by Defendants to purchasers of the Store Brand APAP.

133. In reliance upon Defendants' implied warranties, Plaintiff Mother used the Store Brand APAP as indicated, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

134. Defendants breached their implied warranties to Plaintiffs in that the Store Brand APAP was not of merchantable quality, nor were they safe or fit for their intended use or adequately tested.

1 135. The harm caused by the Store Brand APAP far outweighed their
2 benefit, rendering the Store Brand APAP more dangerous than an ordinary consumer
3 or user would expect and more dangerous than alternative products.

4 136. As a direct and proximate result of Defendants' breach of express
5 warranty, Plaintiffs have suffered permanent injuries, significant pain and suffering,
6 emotional distress, lost wages and earning capacity, and diminished quality of life.
7 Plaintiffs respectfully seek all damages to which they may be legally entitled.

8 **COUNT V: VIOLATION OF CONSUMER PROTECTION LAWS**

9 137. Plaintiffs incorporate by reference the allegations in all prior
10 paragraphs.

11 138. Plaintiff Mother purchased and used the Store Brand APAP for
12 primarily personal use and pain relief during pregnancy, thereby suffering
13 ascertainable losses as a result of Defendants' actions in violation of the consumer
14 protection laws.

15 139. Had Defendants not engaged in the deceptive conduct described in this
16 Complaint, Plaintiff would not have purchased and/or paid for the Store Brand
17 APAP, and Plaintiffs would not have incurred related injury medical costs.

18 140. Defendants engaged in wrongful conduct while at the same time
19 obtaining under false pretenses moneys from Plaintiff for the Store Brand APAP.
20 Those moneys would not have been paid had Defendants not engaged in unfair and
21 deceptive conduct.

22 141. Defendants engaged in the following unfair methods of competition or
23 deceptive acts or practices, which are proscribed by law:

- 24 A. representing that goods or services have characteristics,
25 ingredients, uses, benefits, or qualities they do not have;
26 B. advertising goods or services with the intent not to sell them as
27 advertised; and
28

1 C. engaging in fraudulent or deceptive conduct creating a likelihood
2 of confusion or misunderstanding.

3 142. Plaintiffs were injured by the cumulative nature of Defendants'
4 conduct. The cumulative effect, directed at patients, physicians, and consumers, was
5 to create demand for and sell the Store Brand APAP. Each aspect of Defendants'
6 conduct combined to artificially create sales of the Store Brand APAP.

7 143. Defendants had a statutory duty to refrain from unfair or deceptive acts
8 or trade practices in the design, labeling, development, manufacture, promotion, and
9 sale of the Store Brand APAP.

10 144. Defendants' deceptive, unconscionable, or fraudulent representations
11 and material omissions to consumers, including Plaintiff Mother, constitute unfair
12 and deceptive acts and trade practices in violation of the federal and state consumer
13 protection statutes listed below.

14 145. Defendants' actions, as complained of in this Complaint, constitute
15 unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or trade
16 practices in violation of the federal and state consumer protection statutes listed
17 below.

18 146. Defendants have engaged in unfair competition, or unfair or deceptive
19 acts or trade practices, or has made false representations under the following statutes:

- 20 • 15 U.S.C. §§ 2301–12 (1982);
- 21 • Cal. Bus & Prof. Code § 17200, *et seq.* (Unfair Competition Law
- 22 (“UCL”));
- 23 • Cal. Civ. Code § 17500 (False Advertising Law (“FAL”));
- 24 • Cal. Civ. Code § 1750 *et seq.* (Consumer Legal Remedies Act
- 25 (“CLRA”)).

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1 147. To protect consumers against unfair, deceptive, fraudulent, and
2 unconscionable trade and business practices, and false advertising, each Defendant,
3 as the supplier, manufacturer, advertiser, and seller, are subject to liability under the
4 above legislation enacted against unfair, deceptive, fraudulent, and unconscionable
5 consumer sales practices.

6 148. By knowingly and falsely representing that the Store Brand APAP was
7 fit to be used for the purposes for which they were intended—when in fact they were
8 defective and dangerous—and by other acts alleged, Defendants violated the above
9 statutes, enacted to protect consumers against unfair, deceptive, fraudulent, and
10 unconscionable trade and business practices, and false advertising. The UCL
11 prohibits “any unlawful, unfair, or fraudulent business act or practice and unfair,
12 deceptive, untrue, or misleading advertising and any act prohibited by” Section
13 17500 of the California Business and Professions Code. Section 17500, in turn,
14 prohibits any untrue or misleading statements made in connection with the sale of
15 goods. The CLRA defines as statutorily unlawful certain unfair methods of
16 competition and unfair or deceptive practices. Cal. Civ. Code § 1750 *et seq.*

17 149. By knowingly and falsely representing that the APAP Products were fit
18 to be used for the purposes for which they were intended—when in fact they were
19 defective and dangerous when used during pregnancy—and by other acts alleged,
20 Defendants violated the above statutes, enacted to protect consumers against unfair,
21 deceptive, fraudulent, and unconscionable trade and business practices, and false
22 advertising.

23 150. Defendants’ actions and omissions are uncured or incurable, deceptive
24 acts under the above legislation.

25 151. Defendants had actual knowledge of the defective and dangerous
26 conditions of the Store Brand APAP but failed to take any action to cure such
27 defective and dangerous conditions.

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1 152. Plaintiff Mother relied upon Defendants' misrepresentations and
2 omissions in determining which Store Brand APAP (if any) to ingest.

3 153. Defendants' deceptive, unconscionable, or fraudulent representations
4 and material omissions to consumers constituted unfair and deceptive acts and
5 practices.

6 154. By reason of the unlawful acts in which Defendants engaged, and as a
7 direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and
8 damages.

9 155. As a direct and proximate result of Defendants' violations of the above-
10 listed legislation, Plaintiffs have sustained economic losses and other damages and
11 are entitled to statutory and compensatory damages in an amount to be proven at
12 trial.

13 **COUNT VI: NEGLIGENT MISREPRESENTATION**

14 156. Plaintiffs incorporate by reference the allegations in all prior
15 paragraphs.

16 157. Defendants had a duty to accurately and truthfully represent to
17 consumers, including Plaintiff Mother, and the public that the Store Brand APAP
18 had not been adequately tested and found to be a safe and effective treatment for
19 pregnant women. Defendants breached that duty as their representations were false.

20 158. Defendants failed to exercise ordinary care in the representations
21 concerning the Store Brand APAP while Defendants were involved in its
22 manufacture, sale, testing, quality assurance, quality control, and distribution in
23 interstate commerce, because Defendants negligently misrepresented the Store
24 Brand APAP's high risk of unreasonable and dangerous adverse side effects.

25 159. Defendants also breached their duty in representing to Plaintiff Mother
26 that the Store Brand APAP had no serious side effects when ingested during
27 pregnancy.

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160. As a foreseeable, direct, and proximate result of Defendants' negligent misrepresentations, Defendants knew or had reason to know that the Store Brand APAP had been insufficiently tested or had not been tested at all; and that they lacked adequate and accurate warnings, and created a high risk, or a higher than acceptable reported and represented risk, of adverse side effects. Those side effects include neurodevelopmental disorders in children, such as ASD and ADHD.

161. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

PUNITIVE DAMAGES

162. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

163. Defendants failed to adequately test and study the Store Brand APAP to determine and ensure that the Store Brand APAP was safe and effective prior to releasing them for sale for human consumption.

164. Further, Defendants continued to manufacture and sell the Store Brand APAP after obtaining knowledge and information that they were defective and unreasonably unsafe in that they did not include adequate warnings.

165. Defendants were aware of the probable consequences of the dangerous and defective product, including the risk of neurodevelopmental disorders in children, such as ASD and ADHD, when they suffered prenatal exposure.

166. At all material times, Defendants knew or should have known that the Store Brand APAP was inherently dangerous with respect to the following: the risk of neurodevelopmental disorders in children, such as ASD and ADHD, when they suffered prenatal exposure; pain and suffering; loss of life's enjoyment; and unsuccessful treatments to cure the conditions proximately related to the use of the

1 Store Brand APAP, as well as the other permanent and lasting severe personal
2 injuries.

3 167. Defendants' misrepresentations included knowingly withholding
4 material information from consumers and the public, including Plaintiff Mother,
5 concerning the safety and efficacy of the Store Brand APAP, which deprived
6 Plaintiff Mother of vitally necessary information with which to make a fully
7 informed decision about whether to use the Store Brand APAP.

8 168. At all material times, Defendants also knew and recklessly and/or
9 intentionally disregarded the fact that the Store Brand APAP can cause debilitating
10 and life-altering side effects with greater frequency than safer alternative methods,
11 products, and/or treatments. But Defendants recklessly failed to advise the medical
12 community and the general public, including Plaintiff Mother, of that fact.

13 169. At all material times, Defendants intentionally misstated and
14 misrepresented data; and Defendants continue to misrepresent data so as to minimize
15 the perceived risk of injuries and the rate of complications caused by or associated
16 with the Store Brand APAP.

17 170. Notwithstanding the foregoing and the growing body of knowledge and
18 information regarding the true and defective nature of the Store Brand APAP, with
19 its increased risk of side effects and serious complications, Defendant continue to
20 aggressively market the Store Brand APAP to consumers, including the pregnant
21 community at large, without disclosing the true risk of the complications and side
22 effects.

23 171. When Plaintiff Mother consumed the Store Brand APAP and since
24 then, Defendants have known the Store Brand APAP was defective and
25 unreasonably dangerous without an adequate warning. But Defendants continued to
26 manufacture, produce, assemble, market, distribute, and sell the Store Brand APAP
27 to the pregnant community so as to maximize sales and profits at the expense of the
28 health and safety of expecting mothers in a conscious, reckless, and/or intentional

1 disregard of the likely and foreseeable harm caused by the Store Brand APAP to
2 members of the public, including Plaintiffs.

3 172. At all material times, Defendant have concealed and/or failed to
4 disclose to the public the serious risks and the potential complications associated
5 with the Store Brand APAP, so as to ensure continued and increased sales and profits
6 and to the detriment of the public, including Plaintiffs.

7 173. Defendants' acts and omissions are of such character and nature so as
8 to entitle Plaintiffs to an award of punitive damages in accordance with applicable
9 statutory and common law. Defendants' conduct shows willful misconduct, malice,
10 fraud, wantonness, oppression, or that entire want of care, raising the presumption
11 of conscious indifference to consequences, thereby justifying an award of punitive
12 damages.

13 WHEREFORE, Plaintiffs demand judgment against Defendants individually,
14 and jointly and severally. Plaintiffs also request compensatory damages, punitive
15 damages, or enhanced compensatory damages, together with interest, costs of suit,
16 attorneys' fees, and such further relief as the Court deems equitable and just.

17 **PRAYER FOR RELIEF**

18 Plaintiffs demand judgment against Defendants, individually, and jointly and
19 severally, and prays for the following relief in accordance with applicable law and
20 equity:

- 21 i. Compensatory damages to Plaintiffs for past, present, and future
22 damages, including pain and suffering for severe and permanent
23 personal injuries sustained by Plaintiffs, permanent impairment,
24 mental pain and suffering, loss of enjoyment of life, health and
25 medical care costs, economic damages, together with interest and
26 costs as provided by law;
- 27 ii. Restitution and disgorgement of Defendants' profits;
- 28 iii. Applicable statutory penalties;

- iv. Punitive or enhanced compensatory damages;
- v. Reasonable attorneys' fees as provided by law;
- vi. Past and future costs of all proceedings;
- vii. All ascertainable economic damages;
- viii. Prejudgment interest on all damages as allowed by law; and
- ix. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demands a trial by jury on all issues so triable.

Dated: July 8, 2022

LAW OFFICE OF BALL & YORKE

/s/ Allen R. Ball

Allen R. Ball, Esq.
Brett D. Yorke, Esq.
Attorney for Plaintiffs,
Christine Contreras Individually and as
Mother, General Guardian of A.C. a minor

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